

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0976641	<b>(X3) Date Survey Completed</b>  08/08/2022
<b>Name of Provider or Supplier</b>  Centennial Medical Group	<b>Street Address, City, State</b>  6250 Old Dobbin Lane Suite D, Columbia, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and quality assurance (QA) record review and interview with the general supervisor (GS), the laboratory did not have a detailed QA procedure to monitor, assess, and, when indicated, correct problems identified in the general laboratory system. Findings: 1. The procedure, "Quality Assessment Policy" was reviewed. The procedure was preceded by 2 pages of "Quality Assessment Monitors" which listed QA activities in the left column and dates in the right column. The QA activities were listed under the headings, "General Phase of Testing/Focus Studies," "Pre-Analytical Phase of Testing," "Analytical Phase of Testing," and "Post-Analytical Phase of Testing." 2. Review of the "Quality Assessment Policy" showed that there were no instructions for how to perform the QA duties listed under "Quality Assessment Monitors." 3. During an interview on 08/03/2022 at 2:45 PM, the GS confirmed that the laboratory's QA policy did not include instructions on how to perform the QA activities.</p>
<b>D5311</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions</p>

for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of the standard operating procedure manual (SOPM) and interview with the general supervisor (GS), the laboratory's SOPM failed to define the specimen rejection criteria for each assay based on age of specimen. Findings: 1. The laboratory performed polymerase chain reaction (PCR) testing for multiple panels: 1) severe acute respiratory syndrome coronavirus 2, influenza, and respiratory syncytial virus; 2) sexually transmitted infections; and 3) urinary tract microbiota and antibiotic resistance markers. 2. Each PCR panel's procedure in the SOPM included a "Sample Rejection Criteria" section that stated that specimens would be rejected if "integrity is compromised (too old or damaged)" but did not specify what age was "too old" for each panel. 3. The procedure titled "Laboratory Specimen Collection and Rejection Guidelines" was not specific to the testing performed at the laboratory that was surveyed and did not include sample rejection criteria for the PCR testing panels. 4. During the survey on 08/08/2022 at 2:45 PM, the GS confirmed that the laboratory's SOPM did not define the rejection criteria for age of specimen for each PCR panel.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on laboratory procedure manual and record review and interview with the laboratory staff and the general supervisor (GS), the laboratory did not ensure that the procedure for maintaining the laboratory refrigerator thermometers accurately reflected the current practice in the laboratory. Findings: 1. During an interview on 08/08/2022 at 1:00 PM the laboratory staff stated that monthly each laboratory refrigerator thermometer is checked against a NIST (National Institute of Standards and Technology) certified thermometer in order to verify their calibration. 2. Record review showed that there was no documentation that monthly thermometer calibrations had been performed. This was confirmed by the laboratory staff at 1:00 PM. 3. The procedure, "Equipment Maintenance and Remedial Plan" states that "Thermometers are certified upon receipt by the vendor to ensure their accuracy and consistency" but the procedure did not give instructions on how to perform the monthly thermometer checks. 4. During an interview on 08/08/2022 at 2:45 PM, the GS confirmed that the written procedure manual did not accurately reflect the actual practice of the laboratory.

**D6151**

**GENERAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:

Based on record review and interview with the general supervisor (GS), the GS failed to evaluate and document the performance of all testing personnel (TP). Findings: 1. The laboratory currently has 3 TP listed on the "Laboratory Personnel Report" (CMS-209). 2. A review of competency assessment records from 2021 to 2022 showed that initial training documents for 1 of 3 TP were not present at the time of the survey. 3. During an interview on 08/03/2022 at 3:00 PM, the GS confirmed that the training records could not be located.